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SECTION 1 ADVANCE WARNING AND USERS RESPONSIBILITY

1.1 Advance Warning

Warnings :

- Before applying this product, please read the product instruction carefully.
- Ask for maintenance if any malfunction is found during inspection or operation. Only qualified technical staffs can repair this equipment.
- Keep the equipment and patient being monitored when the equipment is in use.
- The equipment must connected to the power source complied with the technical parameter. Power cable must be

	Type B,Grade I
	Attention:refer to related information
	Warning:surface temperature will exceed 75°C
	Warning:danger of electric shock
	Warning:water-proof
	Power on
	Power off
	Alternating current (AC)

connected to standard socket which has been well connected to the ground. AC stabilizer is recommended to be used when the fluctuation of the voltage exceed 10%.

- Avoid collision and violently vibration.
- Avoid explosion, keep distance from inflammable anesthetics.
- The following are the indication applied in the instruction.

1.2 Users' Responsibility

This humidifier must comply with the regulation of the instruction when it is being installed, operated, maintained or fixed. This equipment must be inspected periodically, users should not apply products with flaws. Broken, missing, distorted contaminated spare parts must be replaced immediately.

The product should not be changed without the manufacturer's authorization. Any losses or damages caused by improper application, or false fixed, the user should take full responsibility.

This brochure offer necessary information to meet the operating need of Humidifier. For the easy operation of the equipment, "ATTENTION" "NOTE" "WARNING" those words are appear in the brochure.

"**ATTENTION**": To remind user avoid false operation.

"**NOTE**": To indicate various function and point out the advantages of the machine.

"**WARNING**": To remind harmful to the patients, users or the equipment.

NOTE: This humidifier is only operated by trained staffs, and under the guidance of the brochure.

- Packaging and transportation: remove the equipment from the transportation package, to inspect if there is any damage in the machine. If any problem found, please keep the packaging material, bill of loading, and other necessary instruction data, and contact with the local supplier in time.
- Service: if any service needed, please contact local suppliers. Please adjust the equipment to get the information of the machine status before asking service, offer the serial number and the detailed information of the problem.

SECTION 2 TECHNICAL REGULATION AND OPERATION MANUAL

2.1 Application of the product

Respiratory Humidifier is a warming and humidifying device designed for ventilators and other positive pressure ventilating systems. The gas is heated and humidified by passing through the surface of the hot water, reduce the stimulation to the cardiopulmonary system by mechanical ventilation. This makes it easy to suck phlegm, and effectively preventing airway obstruction. We can get different temperature by adjusting to different control level, and the temperature can be independently monitored.

Characteristics: temperature and mode digital display, temperature and error alarming, malfunction indicating, thus increase safety , convenience for medical staffs to operate and trouble removal. Suitable for matching with high class ventilators in different levels of hospitals.

Application Ranges: matching with ventilators or other positive pressure ventilating systems, for heating and humidifying gas.

A. Main Functions:

Respiratory Humidifier has automatic (humidity compensation) and non-automatic temperature control, heater wire and non-heater wire mode, invasive and non-invasive mode, and over-heat protecting function. Could match with heating wire circuit.

B. Classification

Safety of the product : Comply with GB9706-2007
Type of anti-electric shock : Type I equipment
Extent of anti-electric shock : Type B applying section
Safe degree in application : Non-AP/APG Type equipment
Operating mode : Continuous

WARNING:

- The use of breathing circuits, chambers or other accessories which are not approved by our company may impair performance or compromise safety.
- Ensure that Invasive mode is set for patients that have bypassed airways.
- Ensure maintenance of grounding integrity by connection to a "hospital grade" receptacle.
- Always disconnect supply before servicing.
- When mounting a humidifier adjacent to a patient ensure that the humidifier is always securely mounted and positioned lower than the patient.
- Ensure that both temperature probe sensors are correctly and securely fitted. Failure to do so may result in gas temperatures in excess of 41°C being delivered to the patient.
- Do not touch the glass tip of the chamber temperature probe during use. Keep blue connectors dry at all times.
- Visually inspect accessories for damage before use.

SECTION 3 SPECIFICATIONS

3.1 Electrical

Supply Frequency	: 50/60Hz
Supply Voltage	: 220V~ - 240V~
Supply Current	: 2.0A max at 220V~
Heater Plate	: 150W
Heater Wire Supply	: 22 ± 5 V~, 2.73 A Max, 50 /60 Hz
Heater Plate Thermal Cutout	: 90 ± 6 °C
Maximum Heater Wire Load	: 8.0Ω .

3.2 Temperature Range

3.2.1 Heater Wire Mode

Invasive Mode	: Chamber outlet: 35.5 to 37°C
Airway Set Point	: 35 to 40°C
Non-Invasive Mode : Chamber outlet	: 31°C
Airway Set Point	: 28 to 34°C

3.2.2 Non Heater Wire Mode

Invasive Mode	: Airway Set point : 37°C chamber temperature limited to 66°C
Non-invasive Mode	: Airway Set point : 31°C (chamber temperature limited to 66)
Display	: Three digit, 0.56 inc, 7 segment LED Range : 10 to 70°C

3.3 Alarm Parameters

High Temperature Alarm	: Causes an immediate, audible and visible alarm at a displayed
	temperature of 41°C or if the airway temperature exceeds 43°C

3.4 Temperature Alarm:

3.4.1 Invasive Mode with Heater Wire Mode : (invasive mode only)

Airway Temperature: After 15 minutes @ 35°C causes an audible alarm and visible Lung indicator lighted on.

Chamber Temperature: After 15 minutes @ 34°C causes an audible alarm and visible Chamber indicator lighted on.This might be caused by falling off temperature sensor or increasing gas flow sharply. Press mute button to silence alarm after sort out the malfunction.

3.4.2 Invasive Mode with Non-Heater Wire Mode : (invasive mode only)

Airway Temperature: After 15 minutes @ 29.5°C causes an audible alarm and visible Lung indicator lighted on.

Chamber Temperature: After 15 minutes @ 29.5°C causes an audible alarm and visible Chamber indicator lighted on. This might be caused by falling off temperature sensor or increasing gas flow sharply. Press mute button to silence alarm after sort out the malfunction.

3.4.3 Non-Invasive Mode with Heater Wire Mode :

Airway Temperature: After 15 minutes @ 29°C causes an audible alarm and visible Lung indicator lighted on.

Chamber Temperature: After 15 minutes @ 28°C causes an audible alarm and visible Chamber indicator lighted on. This might be caused by falling off temperature sensor or increasing gas flow sharply. Press mute button to silence alarm after sort out the malfunction.

3.4.4 Non-Invasive Mode with Non-Heater Wire Mode :

Airway Temperature: After 15 minutes @ 26°C causes an audible alarm and visible Lung indicator lighted on.

Chamber Temperature: After 15 minutes @ 26°C causes an audible alarm and visible Chamber indicator lighted on. This might be caused by falling off temperature sensor or increasing gas flow sharply. Press mute button to silence alarm after sort out the malfunction.

3.5 Sound Pressure Level : Alarms exceed 50 dBA @ 1 m.

3.6 Performance

Invasive Mode : Flow at 6-60 LPM, humidity output >33 mg/L

Non-Invasive Mode: Flow at 6-60 LPM, humidity output >10 mg/L

Warm-up time : Less than 30 minutes.

Recommended ambient temperature range : 18 to 26°C

Maximal working pressure : 2KPa for our reusable chamber.

20KPa for disposable chamber, please refer to chamber specification.

SECTION 4 PANEL INTRODUCTION

4.1 Power Button



The humidifier will power on and turn off by pressing this button.

CAUTION: Although the display is not illuminated, the unit may still be energized. Be sure to disconnect power from the Respiratory Humidifier before servicing.

After power-on the humidifier starts an internal diagnostic routine which checks for possible problems in the humidifier setup. If everything is working correctly, normal control is initiated after beep and "850" shown on three digit display. The humidifier will record and maintain last parameter setting, but always default to invasive mode when it is turned on.

Note: The stuck Power Button for more than 10 seconds will cause audible alarm.

Warning: Please cut out the power before maintenance even the display is not lighted on.

4.2 Mode Button



Switching Non-Invasive and Invasive mode by pressing Mode button. The Mode indicator LED shows the user which mode is selected.

Holding the Mute Button and press Mode Button to switch working mode after enter working menu.



Invasive mode is for use with patients whose upper airways have been bypassed by either a tracheostomy or endotracheal tube. In this mode of operation the humidifier attempts to deliver optimal humidity to the patient (37°C , 44 mg/L , $100 \% \text{ RH}$). This mode is the default mode on power up of the humidifier.

The humidifier normally controls the chamber outlet temperature to 37°C , and the airway temperature to 40°C , maintaining a $+3^{\circ}\text{C}$ temperature gradient along the inspiratory limb.



Non-Invasive mode is suitable only for patients whose natural humidification system (i.e. upper airways) has not been bypassed, but are receiving gas via a facemask or similar.

The humidifier normally controls the chamber outlet temperature to 31°C , and the airway temperature to 34°C , maintaining a $+3^{\circ}\text{C}$ temperature gradient along the inspiratory limb.

4.3 Mute Button



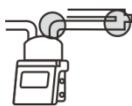
The mute button silences the humidifier's audible alarm. The muted time depends on the alarm condition. In general, alarms will be muted for 2 minutes.

Press Mute Button and Mode Button then release them can enter Working Menu. After enter Working Menu, holding Mute Button to enter relevant function.

Press the Mute Button to check temperature of Chamber and airway.

Attention: The first time to press Mute Button is for silencing alarm, and switching temperature display after second pressing. The indicator will light for showing your which temperature is showing on display.

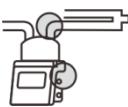
4.4 Indicator light on



Chamber & Airway Probes

Press Mute Button to display Chamber temperature or Airway temperature. Indicator shows which temperature is being showed.

Lights if either the chamber probe or the airway probe is not inserted into the breathing circuit correctly after turn on 15 minutes.



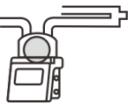
Heater Wire

Lights and alarms if the heater wire adaptor or breathing circuit has not been connected, or is damaged.



Temperature Sensor

Lights and alarms if the temperature Sensor is not correctly plugged into the RHU-01, or the probe is faulty.



Water Out

Lights, alarms and stop heating when there is insufficient water in the chamber. Check water volume in the Chamber and add water to apt water lever, then press Mute Button to silence the audible alarm.



Temperature Alarm

Heater Wire Mode: Lights if the Airway temperature is lower than 35°C under Invasive Mode or lower than 29°C under Non-Invasive Mode when turn on the humidifier for over 15 minutes.

Non-Heater Wire Mode: Lights if the Airway temperature is lower than 29.5°C under Invasive Mode or lower than 26°C under Non-Invasive Mode when turn on the humidifier for over 15 minutes.



See Manual

The humidifier and all accessories should be immediately replaced and sent for servicing.

4.5 Temperature Display

The front panel shows the lower of the chamber or airway temperatures. This display will normally show the chamber temperature (around $37 \pm 0.5^\circ\text{C}$ for invasive mode, and $31 \pm 0.5^\circ\text{C}$ for noninvasive mode). By pushing and holding the mute button for one second, the chamber outlet temperature then the airway temperature is displayed. The display will then revert to normal operation.

This temperature gives an indication of the dew point (in°C) of the gas that is being supplied to the patient. The dew point of a gas is the best indication of both its humidity and energy content. Under normal operation, the displayed temperature will be the chamber temperature, as its control set point is lower. If the temperature is above 70°C , "Hi" will be displayed. If the temperature is below 10°C , "Lo" will be displayed. If HC mode has been enabled the decimal point on the temperature display will flash, Automatic temperature control mode will flash slower than Manual temperature control mode.

4.5.1 Showing Chamber and Airway Temperature

Both the chamber and airway temperature can be displayed by pushing and holding the mute button for 1 second. The temperatures are displayed in the following sequence:

1. Chamber temperature is displayed until two seconds after the mute button is released. The chamber probe indicator will also light to show which temperature is being displayed.
2. The display will blank, and then the airway temperature will be displayed until two seconds after the mute button is released. The airway probe indicator will also light to show which temperature is being displayed.
3. The temperature display will blank again, and revert to normal operation.

SECTION 5 CONNECTION

- 1.** Slide humidification chamber onto humidifier base and connect breathing circuit
- 2.** Connect the temperature probe plug to the blue socket on the humidifier base until an audible click is heard.
- 3.** Push the chamber probe and airway probe into the breathing circuit. Make sure the chamber probe is correctly located in its key-way and that both probes are pushed home. The probe lead can be restrained using breathing circuit clips.
- 4.** Connect the heater wire adaptor plug to the yellow socket on the humidifier base until an audible click is heard.
- 5.** Connect the other end(s) of the heater wire adaptor to the breathing circuit socket(s).
- 6.** The humidification system is now set up and ready for use. After power on, the humidifier will default to invasive mode.

SECTION 6 OPERATION MODE AND SET UP

6.1 Humidifier Operation

Respiratory Humidifier is designed to add heat and moisture to respiratory gases. The gas is passed through a humidification chamber where it is warmed and humidified.

Respiratory Humidifier has two heating systems. The first is a heater plate, which heats the water contained in the humidification chamber, humidifying the air passing through it. The humidifier monitors the temperature of the gas at the chamber outlet with the chamber probe, and controls the amount of power delivered to the heater plate, in order to maintain the chamber set point. Under normal conditions the gas is heated to 37°C in the invasive mode, 31°C for the non- invasive mode.

Humidified gas from the chamber travels through the inspiration limb, where its temperature must be maintained in order to prevent the generated humidity from condensing. This is achieved with a heater wire encapsulated within the inspiration limb. The humidifier maintains the temperature along the inspiration limb by monitoring the temperature at the airway probe and controlling the power delivered to the heater wire. Under normal conditions the gas is heated to 40°C in the invasive mode, 34°C for the non-invasive mode.

An optional, second heater wire, located in the expiratory limb, minimises condensate in this limb.

6.2 Heater wire operation

Humidified gas from the chamber travels through the inspiratory limb, where its temperature must be maintained in order to prevent the generated humidity from condensing. This is achieved with a heater wire encapsulated within the inspiratory limb. The humidifier maintains the temperature along the inspiratory limb by monitoring the temperature at the airway probe and controlling the power delivered

to the heater wire. Under normal conditions the gas is heated to 40°C in the invasive mode, 34°C for the non-invasive mode.

An optional, second heater wire, located in the expiratory limb, minimises condensate in this limb.

6.3 Non-Heater Wire Operation

In this application the RHU-01 maintains the airway temperature at the desired set point (invasive 37°C or non-invasive 31°C) by heating the chamber of water through the heater plate. As the gas cools considerably down the unheated circuit, a water trap circuit must be used to collect the resulting condensate.

6.3.1 Activating Non-Heater Wire Operation

1. Turn on the humidifier with **NO** heated circuit connected.
2. Access the Working Menu by pressing the mute and mode buttons together for one second, the display should show two rows of dashes ‘= = =’. Releasing both buttons will allow the Working Menu to cycle until “End” automatically.
3. Allow the menu to cycle through to “cct” – the circuit identification. Hold mute to access this function.
4. To enable non-heated operation, hold Mute Button and press Mode Button to choose function, the temperature display will show “nhh”. Release both buttons. The humidifier is now configured for non-heated circuits. This setting will be remembered each time the humidifier is turned on.

6.3.2 Deactivating Non-Heater Wire Operation

The simplest way to de-activate non heater wire operation is to connect a heated breathing circuit. But Non-heated circuit mode can not be activated by the same way that remove the heater wire adapter.

6.4 Activating Automatic Humidity Compensation Operation

1. Allow the menu to cycle through to “cct” – the circuit identification. Hold mute to access this function.
2. Allow the menu to cycle through to “HC”, hold mute to access this function.
3. To enable non-heated operation, hold Mute Button and press Mode Button to choose function, the temperature display will show “nhh”. Release both buttons. The humidifier is now configured for non-heated circuits. This setting will be remembered each time the humidifier is turned on.

Attention: As Automatic Humidity Compensation function is on, If the outlet humidity is not maintained at target value, the chamber set point is changed in 0.5°Csteps (minimum setting of 37°C for invasive mode and 31°C for non-invasive mode), in order to provide satisfied humidity.

Attention: After enter "HC",choose temperature control mode by holding Mute Button and pressing Mode Button, "0.0", "1.0", "2.0", "3.0", "4.0", "5.0" is for manual temperature control mode. The digit shows on display means the upper temperature(in°C) than target temperature(invasive mode is 37°C, non-invasive mode is 34°C)

SECTION 7 CLEANING

7.1 Shell

7.1.1 Cleaning

Disconnect the power firstly and clean the shell by a wet cloth or a cotton cloth. Only a little cleaning agent can be added into water which is prepared for the shell cleaning. Liquid, such as organic benzene, ether, benzene and trichloroethylene, can't be used for cleaning.

7.1.2 Disinfection

Use a soft cloth, which is soaked by commonly used water-soluble disinfectant to clean the surface of the shell. Make the disinfectant according to the guidance of the disinfectant manufacturer. Clean the shell carefully in order to avoid any disinfectant seep into the inside of the humidifier. Do not use any organic solvent to clean the shell.

7.2 Components of Humidification Chamber and Adapters

7.2.1 Removing and Replacement of Components

1. Removing of Humidification Chamber

Shut down the humidifier and remove the breathing circuits connected with the humidification chamber; Press the front retainer of the chamber then remove the chamber from the humidifier by pushing it forward.

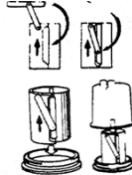
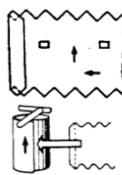
2. Removing Humidification Bottle

Press and push the bottom to remove the upper cover (see the following drawing);

Put an absorbent paper into the absorbent paper bracket following to the drawing;

Put the bracket back to its former place;

Reassemble the upper cover on the humidification bottle.



3. Replacing Washer of the Upper Cover

Remove the upper cover and absorbent paper bracket;

Pull the washer out and replace a new one;

Reassemble all the components.

4. Replacing O-Ring of the Heated Tray

Remove the heated tray from humidification chamber and dismantle the O-Ring;

Put the O-Ring into the seal groove of heated tray and press it in to the groove evenly.

Reassemble the heated tray on the humidification chamber.

ATTENTION : It's wrong to disinfect the humidification chamber when all the components of the chamber are assembled as a whole.

7.2.2 Disinfecting

- ◆ Ensure the surface of heater plate is clean and free from pitting, gouging which may be cleaned by using a moist cloth. Cleaning liquid should be prevented from entering the equipment which may damage the device.
- ◆ The chamber and connectors can be disinfected with 1:500 chlorine-containing disinfectant for 30 minutes.



Do not sterilize adaptors fitted together, or on chambers.



The chambers and adaptors can not be autoclavable.



7.2.3 Power Cable

The power cable should be clean by a wet cloth and soft brush after use. Do not use any sharp things or solvent for plastics for cleaning.

The power cable should be disinfected by a device-disinfectant impregnated cloth. It can't be impregnated into cleaning agent, or be steamed or boiled.

WARNING: Maintain the temperature sensor and heater wire adapter dry.

SECTION 8 ERROR CODES MANUAL

Access the Working Menu by pressing the mute and mode buttons together for 1 second, the display should show two rows of dashes ‘= = =’. Releasing both buttons will allow the Working Menu to cycle automatically until “End” shown on display.

Enter “LFS” function by pushing Mute Button to recognize the error, the error codes shown as below:

Error	Description of Fault
E00	No fault
E01	<i>Disconnect temperature sensor</i>
E02	<i>“POWER ON/OFF” button is stuck</i>
E03	<i>“MODE” button is stuck</i>
E04	<i>“MUTE” button is stuck</i>
E05	<i>5volts and 9volts D.C. Power supply malfunction</i>
E06	<i>Disconnect heater wire</i>
E08	<i>Low temperature of lung</i>
E09	<i>Heater plate sensor faulty</i>
E10	<i>Disconnect 22V or fuse is blown</i>
E11	<i>RL2 relay or Q10 TRIAC is open circuit</i>
E12	<i>RL2 relay or Q10 TRIAC is short circuit</i>
E13	<i>High temperature alarming at output of chamber</i>
E14	<i>High temperature alarming at patients end</i>
E16	<i>Disconnect chamber temperature sensor</i>
E17	<i>Disconnect airway temperature sensor</i>

SECTION 9 WORKING MENU

Access the Working Menu by pressing the mute and mode buttons together for 1 second, the display should show two rows of dashes ‘= = =’. Releasing both buttons will allow the Working Menu to cycle automatically until “End” shown on display.

Display	Description
HC	<p>Humidity Compensation (HC) algorithm Note: HC is inactive while operating under non-heater wire control. Invasive mode, compensation range is 0.0 to 5.0°C (CSP = 37.0 to 42°C) Non-Invasive mode, the compensation range is 0.0 to 5.0°C (CSP = 31.0 to 36.0°C)</p> <p>By pressing the Mute and Mode buttons together for 1 second or pressing the Mute and Power buttons together for 1 second the user can respectively move up or down through the settings listed below. The humidifier will confirm the change with a double beep.</p> <p>‘5.0’ = +5.0°C of chamber compensation ‘4.0’ = +4.0°C of chamber compensation ‘3.0’ = +3.0°C of chamber compensation ‘2.0’ = +2.0°C of chamber compensation ‘1.0’ = +1.0°C of chamber compensation</p>
Cct	<p>Connected breathing circuit identification: “S” = Standard heater wire adapter connected “--” = No heaters detected while under heater wire control</p> <p>Non-Heater Wire Operation</p> <p>To enable non-heater wire operation, press and hold both the mute and mode buttons simultaneously for 1 second. The display will show ‘nhh’ and the humidifier will confirm with an audible beep. Ensure that no heated breathing circuit is connected to the humidifier otherwise the humidifier won’t change operation.</p> <p>To disable non-heater wire mode, repeat the above process or connect a heater breathing circuit</p>
CSP	<p>Chamber set point, in 0.1°C resolution eg. Invasive mode range 37.0°C to 42.0°C. Non-Invasive mode range 31.0°C to 36.0°C.</p>
Cdc	Chamber Duty Cycle (%)
CHP	Chamber Power / Flow ratio (W/LPM)
HP	Heater Plate Temperature (1°C)
Flo	<p>Gas Flow Rate (0.1 LPM) “--” = Unknown Flow (flow measurement not started)</p>
FLr	<p>Gas Flow Rate Range: “--” = Unknown Flow (flow measurement not started) “no” = No flow, (Stand-by) “Lo” = Low flow, (< 3 LPM) “In” = Intermediate flow, (2 to 17 LPM)</p>

	“Hi” = High flow, (> 13 LPM) “ - ” = Ventilated flow detected
ASP	Airway temperature set point (0.1°C)
Adc	Airway Duty Cycle (%)
H2O	Water out number, used to detect the presence of chamber water, calculated from, chamber power / (heater plate temp. – chamber temp.). During selection of this menu the water out indicator will light if the water out number falls below a dry chamber threshold.
LAS	Last Alarm State, the display will blank, and the humidifier’s last alarm will be shown on the indicators. To clear LAS, press and hold the mute and mode buttons for 1 second. The humidifier will beep when LAS has been cleared.
LFS	Last Fault State, refer to section 6.3. To clear LFS, press and hold the mute and mode buttons for 1 second. The humidifier will beep when LFS has been cleared.
SoF	Software version
End	Press the mute button to cycle to the start of the menu, or the diagnostic menu will automatically exit after 6 seconds.

SECTION 10 MATTER NEEDING ATTENTION

10.1 Maintenance

Maintain and inspect the humidifier and its accessories timely to make sure the surfaces of heating tray and heated tray are clean and no-wearing. The surface of heating tray could be clean by wet cloth and be wiped by soft dry cloth.

10.2 Environmental Protection

Humidifier is an auxiliary humidification and heating device of ventilator. It has a certain service life like other medical devices. When the part is determined to be scrapped, please replace it in time.

10.3 Humidification Chamber

The humidification chambers could be infected by special virus since it is connected with the patient’s respiratory track directly. Discarding the untreated waste or residue of the used chambers carelessly could bring pollution to the surrounding environment. Therefore, the used chambers and material in the chambers must be sent to a qualified company for treatment in accordance with the hospital process after properly cleaning and disinfecting.

10.4 Respiratory Humidifier

Respiratory humidifiers should be sent to a qualified company in accordance with the scrap sequence of electronic products and the hospital process for treatment after properly cleaning and disinfecting.

10.5 Transportation and Storage Conditions

Environmental temperature: - 40°C～55°C

Relative humidity: not higher than 93%

Atmospheric pressure: 500hpa～1060hpa

Should be stored in a well-ventilated room without corrosive gases

ATTENTION:

The equipment shall be packed in accordance with the requirements of a contract.

Appropriate icons and logos should be attached on the package.

Avoid violent vibration during transit.

The humidifier should be kept in the operation room for more than 8 hours before being used when the humidifier was stored in improper environment.

RESPIRATORY HUMIDIFIER

RHU-01

Manual Book

